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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/601,952 | 06/23/2003 | Karl A. Jagger | 29985/03-057 | 7910 |

57726 7590 01/24/2007

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| EXAMINER | |
|---|---|
| SONNETT, KATHLEEN C | |
| ART UNIT | PAPER NUMBER |
| 3731 | |

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|---|---|---|
| 3 MONTHS | 01/24/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/601,952 | JAGGER ET AL. | |
| | Examiner | Art Unit | |
| | Kathleen Sonnett | 3731 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *15 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *1-8 and 21-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Response to Arguments*

1. Applicant's arguments, filed 11/15/2006, with respect to the rejection(s) of claim(s) 9, 13, 16, and 17 under 35 USC 102 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Shortt (U.S. 6,948,223).

2. Applicant's arguments, filed 11/15/2006, with respect to the objection to the specification have been fully considered and are persuasive. Therefore, the objection has been withdrawn.

3. Applicant asserts that the device of Jendersee et al. (U.S. 5,836,965) does not anticipate the invention. The examiner considered the first section of the stepped enclosure of Jendersee to be element (44) and the second section to be (proximal smaller tube shown in fig. 3). The inner diameter of (44) is greater than the diameter of the second section (42). However, the claimed invention of the instant application has the first section disposed over a proximal section of the balloon and the second section of the stepped enclosure disposed over the stent. Jendersee discloses the opposite: the first section covers the stent and the second section is disposed over the stent. Therefore, the 35 USC 102 rejections as being anticipated by Jendersee have been withdrawn.

4. Applicant states that "figure 4 and page 7 of the present application and claim 9 all consistently recite the first section has an inner diameter that is greater than the inner diameter of the second section". The examiner points out that the language of claim 9 necessitates that the inner diameter of the first section is greater than *or equal* to the inner diameter of the second section (emphasis added). If this is not the intention of Applicant, claim 9 should be amended.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. **Claims 9 and 13** are rejected under 35 U.S.C. 102(e) as being anticipated by Shortt (U.S. 6,948,223). Shortt discloses a method for fabricating a balloon catheter stent deployment system comprising:

- providing a balloon catheter with an inner tubular shaft disposed within an outer tubular shaft, the inner and outer shafts each having proximal and distal ends, the distal end of the inner shaft extending distally beyond the distal end of the outer shaft (30), and an inflatable balloon having a proximal end attached to the outer shaft near the distal end thereof and a distal end attached to the inner shaft near the distal end thereof (see fig. 2)

- placing a stent over the balloon so that a distal end of the stent is disposed proximally to the distal end of the balloon and a proximal end of the stent is spaced distally from the proximal end of the balloon leaving a proximal section of the balloon uncovered by the stent that extends from the proximal end of the stent to the proximal end of the balloon

- crimping the stent onto the balloon to leave the stent with initial outer diameter (col. 2 ll. 17)

- placing a stepped enclosure over the stent and balloon wherein the stepped enclosure comprising a first section (2nd TFE) having a first inner diameter and that is connected to a second section (3rd Center TFE) having a second inner diameter, the first inner diameter being

greater than or equal to the second inner diameter, the second inner diameter being greater than the initial outer diameter of the stent but in close approximation thereto, the second section of the stepped enclosure being at least as long as the stent, and wherein the first section of the stepped enclosure is disposed over the proximal section of the balloon and the second section of the stepped enclosure is disposed over the stent (col. 2 ll. 12-42),

- inflating the balloon so that the proximal section of the balloon inflates and engages the first section of the stepped enclosure and the stent and balloon disposed beneath the stent and distally of the stent are prevented from substantial expansion by the second section of the stepped enclosure (see proximal pillow gap)

-removing the balloon and stent from the stepped enclosure (col. 2 ll. 40-42).

7. Regarding claim 13, the stepped enclosure is a stepped tube and the second section of the stepped tube extends into the first section of the stepped tube to provide an overlap section between the two sections (see fig. 2).

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. **Claim 12** is rejected under 35 U.S.C. 103(a) as being unpatentable over Shortt in view of Euteneuer et al. (U.S. 5,147,302). Shortt discloses that the method substantially as stated above, but fails to disclose flaring the ends of the stepped tube enclosure.

10. However, Euteneuer et al. discloses that it is old and well known in the art to include flared ends on tubes (50) that are placed over a balloon in order to reduce abruptness of the

leading edge of the tube (col. 4 ll. 7-15). Reduced abruptness allows for easier placement of the tube over the balloon. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Shortt to include flared ends on the stepped tube in order to facilitate placement of the stepped tube over the stent and balloon as made obvious by Euteneuer et al.

11. **Claims 9 and 18** are rejected under 35 U.S.C. 103(a) as being unpatentable over Shortt. The following 103 rejections refer to the improved method disclosed by Shortt whereas the 102 rejections of claims 9 and 13 discussed above are based on the prior art that Shortt discloses as old and well known in the art in the background . Shortt discloses a method for fabricating a balloon catheter stent deployment system comprising:

- providing a balloon catheter (see fig. 7)

- placing a stent over the balloon (see fig. 7)

- crimping the stent onto the balloon to leave the stent with initial outer diameter (col. 2 ll. 54-55)

- placing a stepped enclosure over the stent and balloon

12. In particular, Shortt discloses a stepped enclosure (see fig. 6). The stepped enclosure includes a second section that is at least as long as the stent with a second inner diameter that is greater than the initial outer diameter of the stent but in close approximation to thereto. The enclosure also includes a first portion that covers the proximal section of the balloon. Although Shortt does not expressly disclose that the diameter of this first portion is greater than or equal to the inner diameter of the second section. However, Shortt discloses that the channels of the mold may be made such that the channel includes sections for formations of a proximal pillow (col. 4 ll. 5-7 and 52-59). As seen in fig. 7a, the resulting balloon catheter stent deployment system has a proximal pillow. This would only result if the section of the mold channel that

covers the proximal section of the balloon has a larger diameter than the section covering the stent. Shortt discloses applying pressure to the mold in order to secure the stent to the balloon (col. 2 ll. 60-61). The balloon then inflates and will be allowed to inflate in the section of the stepped enclosure where the diameter is larger, thereby forming the proximal pillow shown in fig. 7a. Therefore, it would have been obvious to one of ordinary skill in the art to modify the method of Shortt to include providing a stepped enclosure comprising a first section covering the proximal section of the balloon, the first section having a diameter greater than the second section disclosed by Shortt which covers the stent in order to achieve the configuration shown in fig. 7a.

13. Regarding claim 18, Shortt discloses the invention substantially as stated above but fails to disclose that the gas used to inflate the balloon has a temperature ranging from about 40° C to about 60° C. However, applicant has not disclosed that the temperature of the gas in the range from about 40° to about 60° C (in spec. 40° to 85° C) is used for a particular purpose or provides any advantage. Furthermore, applicant discloses in the instant specification that the gas may alternatively be delivered at ambient temperature with no disadvantage disclosed (p. 8 ll. 23-26 of instant specification). One of ordinary skill in the art would expect the method of Shortt using an ambient temperature to perform equally as well as applicant's claimed temperature range (40 to 60°C) since no disadvantage is disclosed for using ambient temperature gas for inflation. Moreover, Shortt exposes the inflated balloon to an elevated temperature after inflation to help set the stent, and therefore the gas will reach this temperature. Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Shortt to include the step of delivering gas having a temperature range from about 40° to about 60° C because such a

modification would have been considered a mere design consideration which fails to patentably distinguish over Shortt.

14. **Claims 10 and 11** are rejected under 35 U.S.C. 103(a) as being unpatentable over Shortt in view of Miraki et al. (U.S. 5,704,845). Shortt discloses the invention substantially as stated above, but fails to disclose inserting a protective sleeve over the stent after removing the balloon from the stepped enclosure.

15. However, Miraki et al. discloses that it is old and well known to house a balloon catheter in a protective sleeve (52) before use in order to keep the catheter sterile (col. 3 ll. 19-21). This protective sleeve is put on the finished catheter and is therefore placed over the catheter after the manufacturing process. Therefore, it would have been obvious to one of ordinary skill in the art to modify the method of Shortt. to include inserting a protective sleeve over the stent as made obvious by Miraki et al. in order to keep the stent sterile. Miraki et al. does not disclose keeping the protective sleeve in a position proximal to the balloon prior to and during a manufacturing step and then sliding it over the balloon after the step is completed. However, applicant has not disclosed that keeping the sleeve pre-mounted on the catheter proximal to the stent and then sliding the sleeve over the stent after removing the stepped tube is used for any particular purpose, or provides any advantage. Furthermore one of ordinary skill in the art would expect the modified method of Shortt and applicant's claimed method to perform equally well using either a protective sleeve that is pre-mounted proximally of the stent and then slid over the stent or a protective sleeve that is slide over the stent from the distal end of the stent.

16. **Claim 12** is rejected under 35 U.S.C. 103(a) as being unpatentable over Shortt in view of Johnson (WO02/066095). Shortt discloses the invention substantially as stated above, but fails to disclose that the ends of the stepped tube are flared.

17. However, Johnson discloses that it is old and well known to flare ends of fold over molds used for forming balloon catheter stent deployment assemblies. Johnson discloses that flared edges further facilitate the placement of the assembly in the mold (see page 18 and fig. 9). Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Shortt to include flared ends on the stepped enclosure as made obvious by Johnson in order to facilitate insertion of the assembly in the mold.

18. **Claims 14 and 15** are rejected under 35 U.S.C. 103(a) as being unpatentable over Shortt in view of Motsenbocker et al. (U.S. 6,629,350). Shortt discloses the invention substantially as stated above, but fails to disclose the stepped enclosure (mold) being formed by a plurality of crimping elements each having a stepped leading edge to form the stepped enclosure that are capable of heating the stent and the balloon.

19. However, Motsenbocker et al. discloses that it is old and well known in the art to use a plurality of crimping elements, each having a stepped leading edge (col. 7 ll. 55-59), to form a stepped enclosure wherein the crimping elements are movable between crimping and retracted positions (see abstract). Motsenbocker et al. discloses that this device is superior to stepped tubes because the bore size of a stepped tube limits the diameter of the stent (col. 1 ll. 47 and 63+), which is avoided using the crimping elements. Furthermore, Motsenbocker et al. discloses that heaters may be placed in the crimping elements (col. 13, ll. 7-10) so that heat may be applied during crimping as is well known in the art. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Shortt to include a plurality of crimping elements with stepped edges that are capable of delivering heat as made obvious by Motsenbocker et al. to form the stepped enclosure (mold) in order to gain the advantage of a changing bore size that allows a single mold to hold assemblies of varying diameters.

20. **Claims 16-17 and 19-20** are rejected under 35 U.S.C. 103(a) as being unpatentable over Shortt in view of Jendersee et al. Regarding claims 16 and 17, Shortt discloses the method substantially as stated above but fails to disclose heating the stent and balloon to a temperature ranging from about 50° C to about 85° C degrees.

21. However, Jendersee et al. discloses that it is old and well known to heat a balloon catheter stent deployment assembly to about 65°C (150° F = 65.6° C) to set the assembly (col. 6 ll. 64-67). Although Shortt discloses heating the assembly to about 93° C, Shortt also discloses that the temperature to which the assembly is heated will depends on the materials being used (col. 4 ll. 38-41). Shortt is silent on the materials used for the assembly and if the materials of Jendersee such as a balloon formed of polyethylene terephthalate (PET) are employed using the method of Shortt, it would be obvious to one of ordinary skill in the art to modify the method of Shortt to include the step of heating the stent and balloon to a temperature of about 65° C as made obvious by Jendersee et al. in order to be able to form a balloon catheter stent assembly with the materials of Jendersee et al. using the method and mold of Shortt.

22. Regarding claim 19, Shortt discloses the method substantially as stated above including pressurizing the balloon (col. 2, ll. 60-61), but is silent on a pressure range and time period for the pressurizing step.

23. However, Jendersee et al. discloses that it is old and well known in the art to pressurize the balloon to an internal pressure ranging from about 30 to about 75psi (col. 6, line 64) during the setting of a balloon catheter stent deployment assembly. Since Jendersee et al. has disclosed this range as being appropriate for setting of a balloon catheter stent deployment assembly, one of ordinary skill would be motivated to use this range to carry out the method of Shortt with a reasonable expectation of success. Jendersee et al. fails to disclose a time period

for pressurizing the balloon ranging from 5 seconds to about 1 minute. However, applicant has not disclosed that pressurizing the balloon for a period ranging from 5 seconds to about 1 minute solves any stated problem, is used for any particular purpose, or provides any advantage. Moreover, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art (*In re Aller,* 105 USPQ 233).

24. Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Shortt such that the time period for pressurizing the balloon ranges from 5 seconds to about 1 minute because such a modification would have been considered a mere design consideration which fails to patentably distinguish over modified Shortt.

25. Regarding claim 20, Shortt discloses the invention substantially as stated above but fails to disclose inflating the balloon with a gas having a temperature ranging from about 40 to about 60° C and pressurizing the balloon to an internal pressure ranging from about 30° C to about 75° C for a time period ranging from about 5 seconds to about 1 minute.

26. However, Jendersee et al. discloses that it is old and well known in the art to pressurize the balloon to an internal pressure ranging from about 30 to about 75psi (col. 6, line 64) during the setting of a balloon catheter stent deployment assembly. Since Jendersee et al. has disclosed this range as being appropriate for setting of a balloon catheter stent deployment assembly, one of ordinary skill would be motivated to use this range to carry out the method of Shortt with a reasonable expectation of success. Jendersee et al. fails to disclose a time period for pressurizing the balloon ranging from 5 seconds to about 1 minute. However, applicant has not disclosed that pressurizing the balloon for a period ranging from 5 seconds to about 1 minute solves any stated problem, is used for any particular purpose, or provides any

advantage. Moreover, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art (*In re Aller,* 105 USPQ 233). Regarding the temperature of the gas, applicant has not disclosed that the claimed range (about 40° to about 60° C) is used for a particular purpose or provides any advantage. Furthermore, applicant discloses in the instant specification that the gas may alternatively be delivered at ambient temperature with no disadvantage disclosed (p. 8 ll. 23-26 of instant specification). One of ordinary skill in the art would expect the method of Shortt using an ambient temperature to perform equally as well as applicant's claimed temperature range (40 to 60°C) since no disadvantage is disclosed for using ambient temperature gas for inflation. Moreover, Shortt exposes the inflated balloon to an elevated temperature after inflation to help set the stent. Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Shortt to include the step of delivering gas having a temperature range from about 40° to about 60° C and a pressure of from about 30 to about 75 psi for from about 5 seconds to about 1 minute because such a modification would have been considered a mere design consideration which fails to patentably distinguish over Shortt.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen Sonnett whose telephone number is 571-272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCS 1/12/2007

GLENN K. DAWSON
PRIMARY EXAMINER